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10/815,778	04/02/2004	Gordana Vunjak-Novakovic	103248-010501	8172
67395 7590 03/15/2010 GREENBERG TRAURIG, LLP 200 PARK AVE. P.O. BOX 677 FLORHAM PARK, NJ 07932			EXAMINER SINGH, SATYENDRA K	
			ART UNIT 1657	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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njdocket@gtlaw.com
riosm@gtlaw.com
luposat@gtlaw.com

Office Action Summary	Application No. 10/815,778	Applicant(s) VUNJAK-NOVAKOVIC ET AL.	
	Examiner SATYENDRA K. SINGH	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-43 and 48-111 is/are pending in the application.
- 4a) Of the above claim(s) 12-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/20/09;01/28/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's submissions filed on 12/17/2009 and 01/28/2010 has been entered.

Claims 12-43 and 48-111, as currently amended, are pending in this application.

Claims 1-11 (applicant's elected invention; group Ia) have been previously canceled by applicants. Claims 44-47 have been canceled by the current amendments to claims.

Claims 12-43 (directed to non-elected inventions) remain withdrawn.

Claims 48-68 and newly added claims 69-111 (as currently amended; taken as applicant's elected invention of **group Ia**; directed to **a cartilage repair implant**; elected specie of additive "**growth factor**") are examined on their merits in this office action.

The following contains new grounds of rejections necessitated by applicant's current amendments to pending claims.

Objection to Amended Specification

The amendment filed on 12/17/2009 (for specification on page 8, lines 5) is objected to under 35 U.S.C. 132(a) because it introduces **new matter** into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the substitution of the term "**surgically**" for "**arthroscopically**" in line 5, as currently amended by applicants, raises issues of new matter as it broadens the scope of the process as described in the instant disclosure (arthroscopic surgery being only one of the examples of surgical procedures available for such procedures in the art; i.e. species-genus situation). In addition, applicants, in their

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remarks on page 33 (3rd paragraph, in particular), fail to point out relevant support for such an amendment to the specification as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 70-73 recite the limitations "**the bore** formed ...the patient". There is insufficient antecedent basis for this limitation in the broader claim 69. Appropriate correction is required.
2. Claim 78 recites the limitations "...**the formation of the bore**". There is insufficient antecedent basis for this limitation in the broader claim 69. Appropriate correction is required.
3. Claim 84 recites the limitations "...**the patient's tissue**" in line 11. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.
4. Claim 106 recites the limitations "...formation of **the bore**" in line 4. There is insufficient antecedent basis for this limitation in the broader claim 84. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names **joint inventors**. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 48-111 (as currently presented) **are/remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Hart et al (US 5,782,835; [A]) in view of Stone (US 6,267,786 B1; IDS), Peretti et al (2000; IDS), Hoffman (2002; IDS) and O'Leary et al (US 5,290,558; IDS).

Claims (interpreted herein as a product-by-process) are directed to “a combination for repairing a defect in articular cartilage of a human patient, said combination comprising: **a decellularized allograft osteochondral plug** having a decellularized subchondral bone base and a decellularized cartilage cap, said decellularized allograft osteochondral plug being formed by a method including the steps of:

(a) harvesting, from a human donor, a non-decellularized osteochondral plug having a non-decellularized subchondral bone base and a non-decellularized cartilage cap; and

(b) treating the non-decellularized osteochondral plug to remove cellular material, chondrocytes, pluripotent mesenchymal cells and proteoglycans therefrom; and

a cartilage mixture including **milled allograft cartilage pieces** mixed in a biocompatible carrier, said cartilage mixture **being positionable** in an annular space adjacent said decellularized allograft osteochondral plug, said annular space extending along substantially the entire length of said decellularized allograft osteochondral plug such that said decellularized cartilage cap is spaced from a cartilage layer of the patient and such that said decellularized subchondral bone base is spaced from an adjacent bone layer of the patient, said annular space being sized so as to receive a quantity of said cartilage mixture sufficient for promoting

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chondrocyte migration into and proliferation within said decellularized cartilage cap and for enhancing tissue integration between said decellularized subchondral bone base and adjacent patient tissue.” (see claims 69, in particular)

Claims 84-111 (interpreted as a product or kit) are directed to “in combination, a decellularized osteochondral plug...and a cartilage mixture including milled allograft cartilage pieces...” (see claim 84, in particular)

*"[E]ven though **product-by-process claims** are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir.1985).*

Hart et al [A] (while disclosing apparatus and methods for articular cartilage repair) teach a **cartilage repair implant** (in the form of a pre-shaped bone plug; see Hart et al, abstract, summary of the invention, lines 9-14, and column 3, 4th paragraph, in particular) comprising a sterile, cylindrical shaped structure made of subchondral bone and overlying integral hyaline cartilage cap, wherein said shaped structure has been dimensioned to fit in a drilled bore in a cartilage defect (in the form of a bone plug having a functional fit within the drilled bone hole; see Hart et al, columns 7-9, column 8, lines 50-55; and figures 8-9, in particular). Additionally, Hart et al explicitly suggest the use of various bio-adhesives (known in the art to fill the gap

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between the plug and the hole in the native tissue structure), and additives with the bone plug, such as bone or cartilage **growth-promoting factors** (see Hart et al, column 9, 2nd paragraph, lines 18-24, in particular), including cartilage-derived growth factor, various interleukins, platelet-derived growth factor (PDGF), and bone morphogenic protein (BMP).

However, an osteochondral plug that has been “**decellularized**” such that bone base and cartilage cap are treated to remove cellular material (see claim 69 and 84), is not disclosed by Hart et al.

Stone (IDS) while disclosing non-immunogenic, proteoglycan-reduced soft tissue xenografts teaches a process wherein the immunogenicity of tissue grafts can be reduced by chemical treatment of said grafts such as washing the skeletal tissue in saline and alcohol; subjecting the graft to cellular disruption treatments; and digesting the graft with a proteoglycan depleting factor and/or glycosidase, and optionally following with a capping (i.e. chemical modifications of carbohydrate molecules on the surface of graft tissue) treatment in order to make the graft suitable for implantation purposes (see abstract, summary of the invention, and claims 20 and 21, in particular), wherein the soft tissue xenografts comprise a portion of subchondral bone, and wherein the graft can be implanted in to host cartilage defect site using biological adhesives such as fibrin clot or glue (i.e. biocompatible, polymeric carrier; see column 16, lines 45-55, in particular).

Thus, given the detailed disclosure for the benefits of decellularization of tissue grafts as taught by Stone, it would have been obvious to a person of ordinary skill in the tissue engineering art, at the time this invention was made, to use the process disclosed by Stone in

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order to successfully obtain a cartilage repair implant (i.e. the osteochondral plug as claimed) that has been decellularized in order to remove cellular and other immunogenic materials such as proteoglycans for the benefits and suitability of implantation into host tissue without serious risk of immune rejections.

However, a cartilage repair implant combination comprising an **allograft milled cartilage** mixture, which includes a **biocompatible carrier** at least partially filling the space between the bore and the sidewall portion of decellularized plug, is not explicitly disclosed by the referenced inventions of Hart et al when taken with Stone.

Peretti et al (IDS) disclose the use of cell-based tissue-engineered **allogeneic** implant material for articular cartilage repair in experimental animals, wherein the implant material comprises small pieces (lamb **articular cartilage pieces** chopped under sterile conditions, lyophilized, and sorted through two different meshes to obtain specimens between the range of **500 to 1000 microns**; see Peretti et al, abstract, page 567; Materials & Methods, page 568-572; and figure 1-2, in particular) of sterile, **minced allograft cartilage mixed in thrombin/fibrinogen solution** (i.e. a biocompatible polymeric carrier) with or without allogenic chondrocyte cell preparation (see pages 568-569, in particular) in a buffered solution (such as buffered PBS) containing appropriate antibiotics. Peretti et al explicitly suggest that a composite of fibrin glue and sterile, milled allograft cartilage pieces can effectively serve as a scaffold for chondrocyte transplantation, preserve the original phenotype of the chondrocytes, and maintain the original mass of the implant, which may represent a valid option for addressing the problem of articular cartilage repair (see Peretti et al, abstract on page 567, and discussion on pages 574-

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575, in particular). The claimed limitations of milled cartilage being hyaline and/or fibrocartilage are also met by the disclosure of Peretti et al, wherein the sterile, lamb cartilage chips or small pieces are used to obtain a cell-based allogenic implant construct, as discussed above.

Therefore, it would have been obvious to a person of ordinary skill in the tissue engineering art, at the time this invention was made, to modify the decellularized cartilage repair implant of Hart et al (in view of the disclosure of Stone, as discussed above) such that the decellularized osteochondral plug is surrounded at least partially using a mixture of milled allograft cartilage pieces or mixture in a biocompatible polymeric carrier (such as a solution containing thrombin and fibrinogen), as explicitly disclosed by the invention Peretti et al.

An artisan of ordinary skill in the art would have been motivated to modify the decellularized cartilage repair implant of Hart et al (when taken with the disclosure of Stone as discussed above) because the cited prior art references suggest the incorporation of chondrogenic factors (i.e. various growth factors; Hart et al above), such that it incorporates allograft milled cartilage pieces along with chondrocytes in a biocompatible carrier (Peretti et al, see discussion above) in order to effectively address the problems associated with the articular cartilage repair (i.e. by effectively serving as an efficient scaffold for chondrocyte transplantation, preserving the original phenotype of the chondrocytes, and maintaining the original mass of the implant; see discussion, supra) with reasonable expectation of success.

However, a cartilage repair implant (i.e. a combination as currently claimed) comprising allograft milled cartilage mixture which includes **a biocompatible carrier** such as sodium hyaluronate, gelatin, collagen, chitosan, alginate, or dextran, although clearly suggested (see

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disclosure of Hart et al, column 9, 2nd paragraph, in particular; or use of polymeric carriers such as fibrin glue, buffered PBS, etc. by Peretti et al), is not explicitly taught by the cited references of Hart et al in view of Stone and Peretti et al. In addition, the use of **demineralized bone powder** (see instant claim 75) with the milled allograft cartilage mixture is not explicitly exemplified by the cited references of Hart et al, Stone, Peretti et al.

Hoffman (IDS) discloses the use of various types of **polymeric materials** and hydrogels such as hyaluronic acid, chitosan, gelatin, collagen, dextran, alginate, etc. in biomedical applications, especially for use as cell and drug carriers, and as tissue engineering matrices (see Hoffman, abstract, page 3, and table 1, in particular), wherein said polymeric materials have been shown to be useful in the field of tissue engineering as matrices and/or as bioadhesive carriers, for repairing and regenerating a wide variety of tissue and organs (see page 4, left column, 1st paragraph, right column, last paragraph, and page 9, figure 5, in particular).

O'Leary et al (IDS) disclose the use of lyophilized, **demineralized bone powder** (see title, abstract, column 2, lines 6-21 and columns 3-4 and claims, in particular) in combination with biocompatible carriers that can be used for surgical bone repair in the form of a viscous paste, etc. (see column 5, lines 24-35, in particular).

Thus, to an artisan of ordinary skill in the tissue engineering art, at the time this invention was made, it would have been obvious to successfully substitute biocompatible polymeric carriers that have already been well known in the art, as evidenced by the detailed disclosure of Hoffman, and include deminearlized bone powder with the milled allograft cartilage, as explicitly suggested by O'Leary et al. An artisan of ordinary skill would have been motivated to

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substitute/combine biocompatible carriers (and/or demineralized bone powder) to fill the space or gap between the decellularized plug (as disclosed by Hart et al in view of Stone and Peretti et al) and the sidewall, using allograft milled cartilage pieces because Hoffman clearly provides various benefits of such carriers in tissue engineering (such as for applications as porous, regenerating matrices, or for delivery of growth factors, drugs, or for various structural advantages that effectively support growth of cells responsible for tissue regeneration, etc.), in addition to the benefits of demineralized bone powder for osteochondral repair as suggested by the invention of O'Leary et al.

Given the detailed teachings in the cited prior art references as discussed above, the limitations of various shapes, fitness in the bore, and sizes of the allograft bone plug and diameter ranges, etc. would have been obvious to a person of ordinary skill in the clinical art as evidenced by the fact that Hart et al disclose cylindrical grafts (see Hart et al, figure 8, column8, 2nd and 3rd paragraphs, in particular), the diameter ranges of which would have been obvious design choice depending on the type and measurement of the cartilage defects being treated. Similarly, the limitations "wherein the decellularized plug is lyophilized" to have a particular water content (see instant claims 48-49) would have been obvious to a person of ordinary skill in the tissue engineering art as evidenced by the disclosure Peretti et al that demonstrate the use of lyophilization for the preparation of milled articular cartilage specimens (see Peretti et al above). In the absence of any evidence to contrary, the shape, size, fitness and positioning in the drilled bore or defect, and diameter ranges of the cartilage repair implant plug, and the step of lyophilization to obtain the bone plug with certain water content, would have been obvious parameters for an artisan of ordinary skill in the tissue engineering art to vary and optimize

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depending on the parameters of the cartilage defects being treated and the stability of the decellularized osteochondral plugs desired.

Thus, the combination of decellularized allograft osteochondral plug and the milled allograft cartilage mixture as currently claimed would have been fully contemplated by a person of ordinary skill in the art in view of the combined teachings of the cited references, and would have been obvious to an artisan of ordinary skill in the clinical art at the time the claimed invention was made, especially in the absence of any evidence of criticality for the components and/or the combination as currently being claimed.

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the clinical art at the time the claimed invention was made.

As per MPEP 2144.06, *"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."* *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

As per MPEP 2144.06, *In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents.* *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

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As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Response to Applicant's Arguments

Applicant's arguments filed on 12/17/2009 with respect to pending claims (as they pertain to the previous prior art rejection of record) have been considered but **moot** in view of the new grounds of rejections made in this office action. However, applicant's arguments will be responded herein to the extent they are pertinent to the cited prior art of record:

Applicants seem to be arguing that the decellularized osteochondral plug claimed in this invention is structurally distinct from the osteochondral plug taught by the invention of Hart et al, as it would have (after decellularization process of claim 69, for example) a "honeycomb" like structure which is not disclosed in the cited art (see remarks, pages 26-27, in particular).

This argument is not found to be persuasive because such features upon which applicant relies (i.e., honeycomb structure of the osteochondral plug) are not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, in light of the disclosure provided by the combined teachings in the cited prior

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art of Hart et al, especially in view of Stone (for decellularization process of tissue grafts) and Peretti et al (for teachings the second component, i.e. the milled cartilage pieces/mixture in a biocompatible carrier), it would have been obvious to an artisan of ordinary skill in the clinical art to prepare a combination (i.e. an implant or plug for repairing a defect in articular cartilage with the milled cartilage pieces in a carrier) as claimed. The arguments regarding the interference fit and the depth and/or diameter of the bore as taught by Hart et al being structurally different and/or teaching away is not found to be persuasive because such arrangements in the shape, size, depth and/o other structural features that are required for the osteochondral plug to be fit in the drilled bore or defect site would have been fully contemplated (as per need; see Hart et al, column 7, last paragraph, in particular; and column 8, 3rd paragraph) by an artisan of clinical skill in the art at the time this invention was claimed, as evidenced by the knowledge and relevant devices known in the art for preparing and/or harvesting osteochondral plugs from a donor by Hart et al. In the absence of evidence to contrary, adjustments in such structural arrangements and/or features for osteochondral plugs used for articular cartilage repair using milled cartilage pieces would have been fully contemplated and obvious to an artisan of ordinary skill in the clinical art at the time the claimed invention was made.

The argument that Hart et al do not disclose the use of a cartilage mixture including milled cartilage pieces (see remarks, page 29) is not found to be persuasive because Peretti et al was relied upon to show the fact that allogenic, milled cartilage pieces can be prepared and used in a biocompatible carrier for articular cartilage repair in a patient in need thereof. Moreover, Hart et al suggest such combination by using various art recognized bio-adhesives (see column 9, lines 16-26, in particular) for use with the bone plug as sealant. The arguments regarding the

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Stone reference (see remarks, pages 30-31, in particular) are not found to be persuasive because Stone was relied upon to show the fact that processes of decellularization of xenografts and/or other biological tissue grafts have been known and would have been considered advantageous by an artisan of ordinary skill in the art, especially when using allograft or xenograft materials (that have been commonly associated with immunological problems, host-rejections, etc.) for tissue repair. Thus, in the absence of evidence the contrary, the combination as claimed (see claims 69 and 84, in particular) would have been obvious to a person of ordinary skill in the clinical art at the time the claimed invention was made (see the 103a rejection above over the amended claims).

Conclusion

NO claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JON P. WEBER can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Satyendra K. Singh/
Examiner, Art Unit 1657

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657